

configuration wherein said needle trap traps said sharpened distal end of said needle;

(b) a limiting apparatus formed upon said needle trap and engageable with said at least one recessed change in profile formed upon said needle for limiting the distance said needle trap travels upon said needle from said first retracted and second operative configurations; and

(c) a biasing apparatus for urging said needle trap of said hub towards said sharpened distal end of said needle.

(N9)

#### REMARKS

The foregoing Amendment and remarks which follow are responsive to the non- final Office Action mailed December 15, 1999 in relation to the above-identified patent application. In that Office Action, Claims 181-188 were rejected under 35 U.S.C. §102(b) as being anticipated by MORRISON (i.e., United States Patent No. 5,584,818). In this regard, the Examiner directed to Applicants' attention to Figures 18-21 thereof.

With respect to the rejection of the claims under 35 U.S.C. §102(b), Applicants respectfully submit that the Morrison reference neither teaches nor discloses a needle protective device comprising, inter alia, a needle guard slidably mounted upon a needle, whereby the needle has a proximal end and a sharp distal end with at least one recessed change of profile formed thereon, and the needle guard has a removable needle trap, the latter having a limiting apparatus engageable with said at least one recessed change in profile for limiting the distance the needle trap travels upon the needle. In this respect, the safety hypo-dermic needle and shielding cap assembly disclosed in Morrison comprises the combination of a safety shield and a leaf spring. The safety shield is movable about the length of the canula, and is biased toward the distal end thereof by the leaf spring. Once the safety shield has been extended to the distal-most end of the canula, a cover

plate formed on the cover spring covers the distal-most end of the needle tip with the leaf spring preventing further distal movement of the safety shield, thus causing the same to remain in relatively fixed position relative the distal end of the needle.

The present invention, in contrast, does not incorporate a leaf-spring. Moreover, with respect to the claims as amended, there is no biasing member whatsoever for urging the needle guard having a needle trap formed therein for trapping the sharp and distal end of the needle. In this respect, the Examiner's attention is directed to the embodiment depicted in Figure 106, and discussed in the specification at Page 83, lines 18-85, line 11. In this respect, the recessed change in profile formed upon the needle forms a unique mechanism by which the distance the needle trap travels upon the needle is limited, particularly when the same assumes the operative configuration to trap the sharp and distal end of such needle.

As is well-known, anticipation cannot be established unless a single prior art reference discloses each and every element of the claimed invention. Structural Rubber Co. vs. Park Rubber Co., 749 F.2d 707, 223 USPQ 1264 (Fed.Cir. 1994). Moreover, for anticipation to apply, all of the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of the prior art. See, e.g., Studiengesellschaft Kohle m.b.H vs. Dart Industries, 762 F.2d 724, 726, 220 USPQ 841, 842, (Fed.Cir. 1984). Accordingly, by virtue of the fact that Applicant's apparatus for introducing an intravenous catheter neither includes a leaf spring, nor any other apparatus for that matter for biasing the needle trap forward, Applicants respectfully submit that rejection of the newly-amended claims under §102 cannot be maintained.

In light of the foregoing amendment and remarks, Applicants respectfully submit that all of the claims are allowable and are in a condition for immediate allowance. Early notice to that effect is respectfully requested.

To the extent the Examiner has any questions, requires additional information, or has any suggestions to expedite resolution of any outstanding matters, he is invited to contact Applicants' counsel at the number listed below.

Respectfully submitted,

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